

27. (Previously added) The method of claim 1, wherein the agent is selected from the group consisting of a growth factor, oxytocin, and prolactin.

28. (Previously withdrawn) The method of claim 16, wherein the agent is a nonabsorbable biocompatible solution.

29. (Previously withdrawn) The method of claim 16, wherein the agent is selected from the group consisting of mannitol and sorbitol.

30. (Previously withdrawn) The method of claim 16, wherein the agent is selected from the group consisting of a sugar, glucose, glycerol, sucrose, raffinose, fructose, and lactulose.

31. (Previously withdrawn) The method of claim 16, wherein the agent is selected from the group consisting of polyethyleneglycol (PEG), maltodextrin, dextran, and dextran 70.

32. (Previously withdrawn) The method of claim 16, wherein the agent is an extract from a natural herb.

33. (Previously withdrawn) The method of claim 16, wherein the agent is selected from the group consisting of a growth factor and prolactin.

#### REMARKS

Claims 1, 6, 8-11 and 22-27 are now pending in the application. Claims 1, 8, 9 and 10 have been amended. Claims 2-5 were previously cancelled. Claims 12-21 and 28-33 were previously withdrawn. Claim 7 has been cancelled. Support for the new claims can be found in the specification, particularly pages 5 and 10, as well as Table III on page 15.

Examination and consideration of the claims are respectfully requested. No new matter has been added by way of amendment.

Previous Rejection of Claims Under 35 U.S.C. §102(b)

Claims 1, 8, 10, 22, 25 and 27 were previously rejected under 35 U.S.C. § 102(b) as being anticipated by Falconer *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins.

Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Falconer *et al.* describes an in vivo experiment in rabbits to measure the effect of prolactin and ouabain on mammary alveolar tissue. Falconer *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Dextran Blue 2000) as an agent to increase the secretion of ductal fluid into a breast duct. In fact, as evidenced on page 182, Column 2, lines 13-15, Falconer *et al.* explicitly states that Dextran Blue 2000 is used to "...locate the injected glands at the time of removal". Similarly, Falconer *et al.* does not teach a method for administering intraductally to a patient an agent that increases the secretion of ductal fluid into a breast duct. As evidenced on page 185, Column 1, lines 4-8, Falconer *et al.* explicitly states that "From these results we conclude that *in vitro* and *in vivo* prolactin has significant influence upon Na<sup>+</sup> and K<sup>+</sup> content (and therefore Na<sup>+</sup>/K<sup>+</sup> ratio) of mammary alveolar tissue". Alveolar tissue is comprised of glandular tissue and secreting cells that surround the ductal system (see page 182, Column 2, lines 29-33). Therefore, Falconer *et al.* does not disclose that prolactin and ouabain increases water content in breast ducts, but instead, discloses an increase in water content of the surrounding alveolar tissue. There is no teaching or suggestion in Falconer *et al.* of an agent that increases the secretion of ductal fluid into a breast duct.

Accordingly, the rejection Falconer *et al.* should not be applied to newly amended Claims 1 and 8, nor dependent Claims 10, 22, 25 and 27 for all of the reasons stated above.

Claims 1, 6, 8, 10, 22, 25 and 27 were previously rejected to under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos *et al.*, and U.S. Patent No. 6,235,305 to Mullins.

As mentioned previously, Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Martyn *et al.* describes an *in vivo* experiment in rabbits to measure the effect of prolactin and progesterone on lipogenic-enzyme activity and glycerolipid synthesis. Martyn *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Blue Dextran 2,000,000) as an agent to increase the secretion of ductal fluid into a breast duct. In fact, as evidenced on page 326, Column 1, lines 28-41, as well as Table 4 on page 326, Blue Dextran mixed with Phosphate-buffered saline had no effect on fatty acid synthesis. Similarly, there is no teaching or suggestion that any agent described in Martyn *et al.*, including Blue Dextran, would increase secretion into a breast duct.

Accordingly, the rejection Martyn *et al.*, should not be applied to newly amended Claims 1 and 8, nor dependent Claims 10, 22, 25 and 27 for all of the reasons stated above.

#### Previous Rejection of Claims Under 35 U.S.C. §103(a)

Claims 1, 8-11, 22, 25 and 27 were previously rejected under 35 U.S.C. 103 as being unpatentable over Falconer *et al.*, *supra* in view of U.S. Patent No. 6,221,622 to Love. Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Applicants submit that Falconer *et al.* neither anticipates the amended claims nor are they made obvious by Love. Because Falconer *et al.* does not teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. Love does not disclose an agent

to increase the secretion of fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Love does not recite any agent that increases the amount of secreted fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Combining Falconer *et al.* with the Love cannot make up for the deficiencies of Falconer *et al.* with respect to the claimed invention. Neither Falconer *et al.* nor Love teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, nor can they be combined to anticipate all the elements of the claimed invention. *Prima facie* obviousness has not been established under such conditions.

Accordingly, the rejection should not be applied to newly amended Claims 1 and 8, nor dependent Claims 10, 22, 25 and 27 for all of the reasons stated above.

Claims 1, 8-11, 22, 25 and 27 were previously rejected under 35 U.S.C. 103 as being unpatentable over Martyn *et al. supra* in view of U.S. Patent No. 6,221,622 to Love. Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Martyn *et al.* does not teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. Love does not disclose an agent to increase the secretion of fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Love does not recite any agent that increases the amount of secreted fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Combining Martyn *et al.* with the Love cannot make up for the deficiencies of Martyn *et al.* with respect to the claimed invention. Neither Martyn *et al.* nor Love teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, nor can they be combined to anticipate all the elements of the claimed invention.

Accordingly, the rejection should not be applied to newly amended Claims 1 and 8, nor dependent Claims 10, 22, 25 and 27 for all of the reasons stated above.

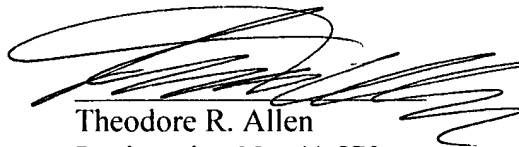
### CONCLUSIONS

It is believed that the claims are in condition for allowance. Early notice to this effect is solicited. Attached is a marked-up version of the changes being made by the current amendment. Applicant asks that all claims be examined and allowed.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855, referencing Attorney Docket No. 12.023011.

Respectfully submitted,

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